



DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION

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June 16, 1997

Dear Colleague:

On September 11 and 12, 1997, FDA in conjunction with other Federal agencies, will convene a hearing under Part 15 of its regulations on benzodiazepines and related substances. The one and one-half day hearing will be held at the Renaissance Hotel, Washington, D.C. The purpose of the hearing will be to gather evidence on assessing the abuse potential of benzodiazepines and related compounds and to develop criteria that will distinguish the substances to address their appropriate scheduling under the Controlled Substances Act (CSA). The information collected will be used to develop industry guidance on the types of evidence needed to assess the abuse potential and dependence producing characteristics of benzodiazepine substances.

Benzodiazepines and related drug substances have consistently ranked among the most widely prescribed drug products in the United States. These products are used extensively as anxiolytics, sedatives, and hypnotics. Concomitant with the widespread use of these products have been concerns associated with benzodiazepine abuse, misuse, and the level of domestic and international control applied to these substances.

The attached Federal Register notice sets forth the public hearing topics and questions for consideration. In addition, the notice provides information on how individuals and organizations can submit information to the public administrative record, and provide evidence during the hearing. Hearing participants will present information directly to a Federal panel with representatives from FDA, the National Institute on Drug Abuse, the Substance Abuse and Mental Health Services Administration, and the Drug Enforcement Administration.

Thank you for your interest in this important public health issue.

Sincerely yours,

Stuart L. Nightingale, M.D.  
Associate Commissioner  
For Health Affairs

Enclosure: